

REGULATORY STATUS

OVERVIEW: The Regulatory Status module determines the statutes and regulations that govern the chemicals and industrial processes in the use cluster. Although federal environmental regulations are typically assessed in a CTSA, this module also provides guidance in conducting searches of other Federal regulations and state and local regulations that may be pertinent to the use cluster being assessed or the group performing the evaluation.

GOALS:

- Determine the pertinent laws and regulations, including those governing use and release to the workplace or environment, affecting the chemicals, processes, and technologies in the use cluster or the use cluster industry.
- Assist in the evaluation of economic and social costs and benefits of the use of a particular chemical, process, or technology by determining the regulatory requirements that lead to costs of compliance (such as treatment costs, permit costs, and reporting costs) and public disclosure of environmental information, possibly affecting public relations.

PEOPLE SKILLS: The following lists the types of skills or knowledge that are needed to complete this module.

- Ability to identify laws and regulations affecting the chemicals and technologies in the use cluster or the target industry, including environmental, consumer product safety, and occupational safety and health laws and regulations.
- Ability to do legal research and search legal data bases.
- Legal expertise required to interpret laws and regulations and their application in a particular jurisdiction or particular situation.

Within a business or DFE project team the people who might supply these skills include environmental compliance managers and corporate attorneys, particularly those specializing in environmental compliance. Environmental consultants and law firms can also provide the skills and knowledge necessary.

DEFINITION OF TERMS:

Code of Federal Regulations (CFR): The official codification of federal regulations that were originally published in the daily *Federal Register*. *Citation note:* In a citation to the CFR (e.g.,

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40 CFR 129), the first number is the number of the title on a particular topic (Title 40 covers "Protection of Environment"), and the second number indicates the "part" or the section number (part 129 regulates "Toxic Pollutant Effluent Standards"). *Updating*: If the CFR part or section has been repealed or amended, the List of CFR Sections Affected (LSA) will provide a citation for the current material in the *Federal Register*.

Federal Register (Fed. Reg.): A daily publication of proposed and final federal regulations.

Citation note: In a citation to the *Fed. Reg.*, the first number indicates the volume and the second number indicates the page. A complete citation also includes the date of publication. For example, 60 *Fed. Reg.* 5320 (Jan. 27, 1995) is Volume 60, page 5320, published on January 27, 1995.

Regulation: A rule or order having the force of law issued by the executive branch of government (e.g., by a federal administrative agency) to implement a statute.

Statute: A law enacted by the legislative department of government, whether federal, state, city, or county.

United States Code (U.S.C.): The official text of federal statutes. *Citation note*: In a citation to the Code (e.g., 49 U.S.C. 1261), the first number is the number of the title for a particular topic (Title 49 covers "Transportation"), and the second number is the section number of the statute. The United States Code Annotated (U.S.C.A.) and the United States Code Service (U.S.C.S.) follow the same numbering system and include annotations to federal regulations implementing the particular Code section. *Updating*: All of these texts are updated regularly by pocket parts at the end of each volume and/or supplementary volumes.

APPROACH/METHODOLOGY: The following presents a summary of the approach or methodology for identifying regulations affecting substitute chemicals, processes, or technologies. Further methodology details for Steps 2, 3, and 4 follow this Section.

- Step 1: Obtain chemical identities including CAS RNs and synonyms from the Chemical Properties module. Identify the industry sector and specific process type (e.g., printing - lithographic) from the Chemistry of Use & Process Description module.
- Step 2: Search secondary materials to preliminarily determine the statutes and regulations that apply to a particular chemical, process, or technology.
- Step 3: Review federal statutes by reviewing codifications (e.g., *United States Code*) or looseleaf services (e.g., *Environment Reporter*).
- Step 4: Review the federal regulations by original publication, codification, looseleaf service, or computer data base.

- Step 5: Search case law for court interpretations of federal statutes and regulations. In order to perform a thorough and comprehensive regulatory analysis, if time and resources permit, an environmental attorney, qualified law student, or paralegal should conduct an up-to-date search of case law from the federal courts to determine if there have been any court interpretations of statutes and regulations applicable to the chemical, process, or technology, and to determine the status of challenged regulations. Official case reporters can be used, such as *U.S. Reports*, or unofficial reporters, such as *United States Law Week*, *Supreme Court Reports*, *Federal Reporter*, and *Federal Supplements*. Other sources include *Environment Reporter Cases* and WESTLAW® or LEXIS® computer data bases.
- Step 6: Review state statutes, regulations, and case law. Most states are administering federal environmental and occupational health and safety regulatory programs with federal approval and may have stricter and/or different requirements than federal statutes and regulations. Therefore, for a specific facility location it may be desirable to research state law as part of the regulatory analysis. In addition to official codifications of the state statutes and regulations that may be available in a major law library, the *Environment Reporter* is a valuable resource for locating state environmental statutes and regulations. For completeness, state court decisions should also be reviewed for interpretations of state statutes and regulations. State statutes and case law can also be searched using WESTLAW® or LEXIS® computer data bases.
- Step 7: Review local statutes and regulations. In some states, local governments also administer environmental statutes and regulations and may have different and stricter requirements than federal and state statutes and regulations. For a specific location, it may be desirable to review these local requirements, which can be obtained by consulting the local government, by visiting a local law library, or by consulting a local industrial development office which may have special packets concerning local regulations. For completeness, state court decisions should be reviewed for interpretation of local statutes and regulations.
- Step 8: Provide the results of the search to the Risk, Competitiveness & Conservation Data Summary module. If a control technology would be required for one of the substitute chemicals in the application being evaluated, provide these requirements to the Control Technologies Assessment module. Additional regulatory information, such as specific disposal requirements, should be provided to the Regulatory Status module. If a chemical is planned for a ban or phase-out, provide this information to the Market Information module.

METHODOLOGY DETAILS: This section presents methodology details for completing Steps 2, 3, and 4. If necessary, additional information on these and other steps can be found in the published guidance.

Details: Step 2, Searching Secondary Sources

There are several commercial sources that can be used to preliminarily determine the statutes and regulations that apply to a particular chemical. *These sources will provide only a brief summary of the major regulations governing a chemical, however. They are not official sources and are not updated as often as the federal regulations. Even sources that are updated frequently (e.g., by supplements or a looseleaf service) cannot be relied upon as authoritative law.*

Examples of secondary sources include:

- *EPA Registry of Lists*: A data base of federal regulations applicable to specific chemicals that can be searched by chemical. It is maintained and updated by EPA for its own use and is not generally available to the public.
- *The Suspect Chemicals Sourcebook*: This reference shows what regulations apply to any given chemical. It directs the researcher to a Source List (e.g., Clean Water Act Section 311) which provides capsule descriptions of each chemical and complete chemical listings for each regulation. In many cases, the original regulation is reprinted (e.g., from the *Code of Federal Regulations* or the *Federal Register*).
- *Law of Chemical Regulation and Hazardous Waste*: This source is a legal treatise with an update service that keeps it fairly current. It analyzes not only environmental laws, but also occupational safety and health regulations, food additive regulations, and consumer product regulations with footnotes to key statutory and regulatory texts. Since it is not organized by chemical name, there is no simple way to find all the regulations governing a particular chemical. The treatise is organized by broader topic, such as "Regulation of the Generation, Transportation, Storage, and Disposal of Hazardous Waste."
- *Regulatory Profiles*: Profiles developed by EPA listing pertinent environmental regulations affecting specific industries. See the section on data sources for examples of EPA regulatory profiles that are currently available.
- *Topical Material*: Treatises and looseleaf services exist for specific federal statutes. See the section on data sources for some examples of guides to the Emergency Planning and Community Right-to-Know Act (EPCRA) and the Toxic Substances Control Act (TSCA). These can be searched for applicability to the chemicals of interest.

Details: Steps 3 and 4, Searching Federal Statutes and Regulations

Identifying Applicable Statutes and Regulations

Federal statutes that may apply include laws governing releases of pollutants to air, land, or water, as well as laws governing the shipment of hazardous materials, the safety of consumer products containing hazardous chemical ingredients, and the exposure of workers to chemicals in the workplace. The discussion that follows identifies some of the key provisions of several federal statutes. It does not attempt an in-depth analysis nor does it list all the provisions that may apply.

The Clean Air Act (CAA) (42 U.S.C. 7401-7671q): Governs emissions of air pollutants to the environment. In addition to the *Code of Federal Regulations*, federal air regulations can be located easily in the *Environment Reporter (ER) Federal Regulations Binders*. Examples of key provisions include:

- National Ambient Air Quality Standards (NAAQS): EPA has established NAAQS for six criteria pollutants:
 - (1) Sulfur dioxide (SO₂).
 - (2) Nitrogen dioxide (NO₂).
 - (3) Carbon monoxide (CO).
 - (4) Ozone.
 - (5) Lead.
 - (6) Particulate matter (PM-10).
- Hazardous Air Pollutants (HAPs): The National Emissions Standards for Hazardous Air Pollutants (NESHAPs) control 189 pollutants listed at 42 U.S.C. 7412. The regulatory standards for these substances are spelled out at 40 CFR 61. Sources must also prepare and implement risk management plans with the Chemical Safety and Hazard Investigation Board.
- State Implementation Plans (SIPs): The states are authorized to establish programs for implementing the CAA. Regulations for each SIP can be found at 40 CFR 52. These can also be found in the *ER Federal Regulations Binder* at Tab 125.
- Chlorofluorocarbons (CFCs) or halons will be phased-out under Title VI of the CAA Amendments, at 42 U.S.C. 7671.

The Comprehensive Environmental Response, Compensation, and Liability Act

(CERCLA) (42 U.S.C. 9601-9675): Governs the cleanup of sites where hazardous substances have been released or disposed. Examples of key provisions include:

- A list of "hazardous substances" (see 42 U.S.C. 9601 for definition; see 40 CFR 302.4 for list of chemicals).
- Reportable Quantity (RQ) for releases of chemicals (see 40 CFR 302.4). If there is a release of the substance greater than the RQ, any person in charge of the facility must notify the National Response Center.

The Clean Water Act (CWA) (33 U.S.C. 1251-1387): Governs the discharge of pollutants to United States waters, but does not cover ground water. Federal water pollution regulations can be found in the *ER Federal Regulations Binder* and the *Code of Federal Regulations*. Examples of key provisions include:

- The National Pollutant Discharge Elimination System (NPDES). NPDES permits are needed for point source discharges into surface waters (see 33 U.S.C. 1342 & 40 CFR 122.2). Permits include limits on discharge of specific chemicals as required by regulations for specific industry categories.
- "Priority pollutants" are listed at 40 CFR 122, Appendix D.
- National effluent standards source categories. The CWA has a system of minimum national effluent standards for several industry categories (see 33 U.S.C. 1316 for the categories and 40 CFR 400-460 for effluent guidelines and standards; toxic pollutants regulated under these standards are found at 40 CFR 401.15).

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The Emergency Planning and Community Right-To-Know Act (EPCRA) (42 U.S.C. 11001-11050; also known as Superfund Amendments and Reauthorization Act [SARA] Title III): Requires reporting to EPA for toxic chemical releases to the environment and off-site transfer of chemicals. Reports are publicly available. Facilities must file an annual Toxic Release Inventory for each chemical listed at 40 CFR 372.65 if the facility has more than 10 employees and manufactures, processes, or otherwise uses amounts of chemicals in excess of the threshold reporting amount (see 40 CFR 372.25).

The Federal Food, Drug, and Cosmetic Act (FFDCA) (21 U.S.C. 301-395): Governs chemicals used as food additives or in cosmetics.

The Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) (7 U.S.C. 136-136y): Governs chemicals used as active ingredients in pesticides.

The Hazardous Materials Transportation Act (HMTA) (49 U.S.C. 1801-1812): Governs shipments of hazardous materials in commerce by road, air, rail, and water. Examples of key provisions include:

- The listing of materials that are hazardous to transport in the Hazardous Materials Table (49 CFR 172.101), which also contains regulations for packaging, labeling, and transportation.

The Consumer Product Safety Act (CPSA) (15 U.S.C. 2051-2084) and **The Hazardous Substances Act (HSA)** (15 U.S.C. 1261-1277): Governs the safety of consumer products, including hazardous chemical ingredients. "Hazardous substances" defined by 15 U.S.C. 1261(f)(1)(A) or by any regulation issued by the Consumer Product Safety Commission are subject to labeling requirements, and the Commission may ban a product through regulation.

The Occupational Safety & Health Act (OSHA) (29 U.S.C. 651-678): Governs the exposure of workers to chemicals in the workplace. Examples of key provisions include:

- The Hazard Communication Standard, explained in 29 CFR 1910.1200, mandates notice requirements, labeling requirements, and the availability of Material Safety Data Sheets (MSDSs). Requires employers to inform and train employees about hazardous chemicals.
- Hazardous air contaminants in the workplace are controlled by Permissible Exposure Limits (PELs). These are found in 29 CFR 1910.1000 Table Z-1-A.

The Resource Conservation and Recovery Act (RCRA) (42 U.S.C. 6901- 6991): Governs the generation, transport, treatment, storage and disposal of hazardous chemical waste. In addition to the *Code of Federal Regulations*, the *ER Federal Regulations Binder* is a good resource to locate regulations on hazardous waste. Key provisions include:

- Definition of hazardous waste:
Solid waste as defined by RCRA that fits any category below is hazardous waste subject to RCRA regulation:

- Listed wastes (see 40 CFR 261 - four lists).
- Characteristic wastes (e.g., ignitable, corrosive, reactive, or toxic wastes. See 40 CFR 261.2).
- Substances derived from listed wastes.
- Substances mixed with either listed or characteristic wastes.
- Treatment, Storage, and Disposal Facility (TSDF) regulations: Permitting requirements are found at 40 CFR 264-265, 270).

The Toxic Substances Control Act (TSCA) (15 U.S.C. 2601-2692): Governs manufacturing, use, and disposal of toxic chemicals; requires premanufacturing notices for new chemicals, and comprehensive reporting for certain existing chemicals. In addition to the *Code of Federal Regulations*, the *ER Federal Regulations Binder* is a good resource to locate TSCA regulations. TSCA regulates "chemical substances and mixtures" as defined in the act and regulations (40 CFR 710). Substances regulated under FIFRA and FFDCA are exempt.

Codifications of Federal Statutes

Codifications of federal statutes include:

- *United States Code* (U.S.C.).
- *United States Code Annotated* (U.S.C.A.).
- *United States Code Service* (U.S.C.S.).

Other publications which are useful tools for locating the text of environmental statutes include:

- *Environmental Law Reporter Statutes Binder*.
- *ER Federal Laws Binder* (published by the Bureau of National Affairs [BNA]).

These publications do not contain other federal laws, such as the Occupational Safety and Health Act (OSHA), which may apply to the chemical being researched. Other looseleaf services specialize in a particular area, such as:

- *Chemical Regulations Reporter* (published by BNA).
- *Occupational Safety and Health Reporter* (published by BNA).
- *Food and Drug Law Reporter* (several publishers).

Locating Federal Regulations

Sources that can be used to access the regulations in text form include:

- Annotations to the U.S.C.A. or U.S.C.S., which cite regulations that implement particular statutory provisions.
- Index to the *Code of Federal Regulations*.
- *ER Federal Regulations Binder*.
- *Federal Register* where the regulation was originally published (also contains explanatory materials not codified in the CFR).
- Computer data bases.

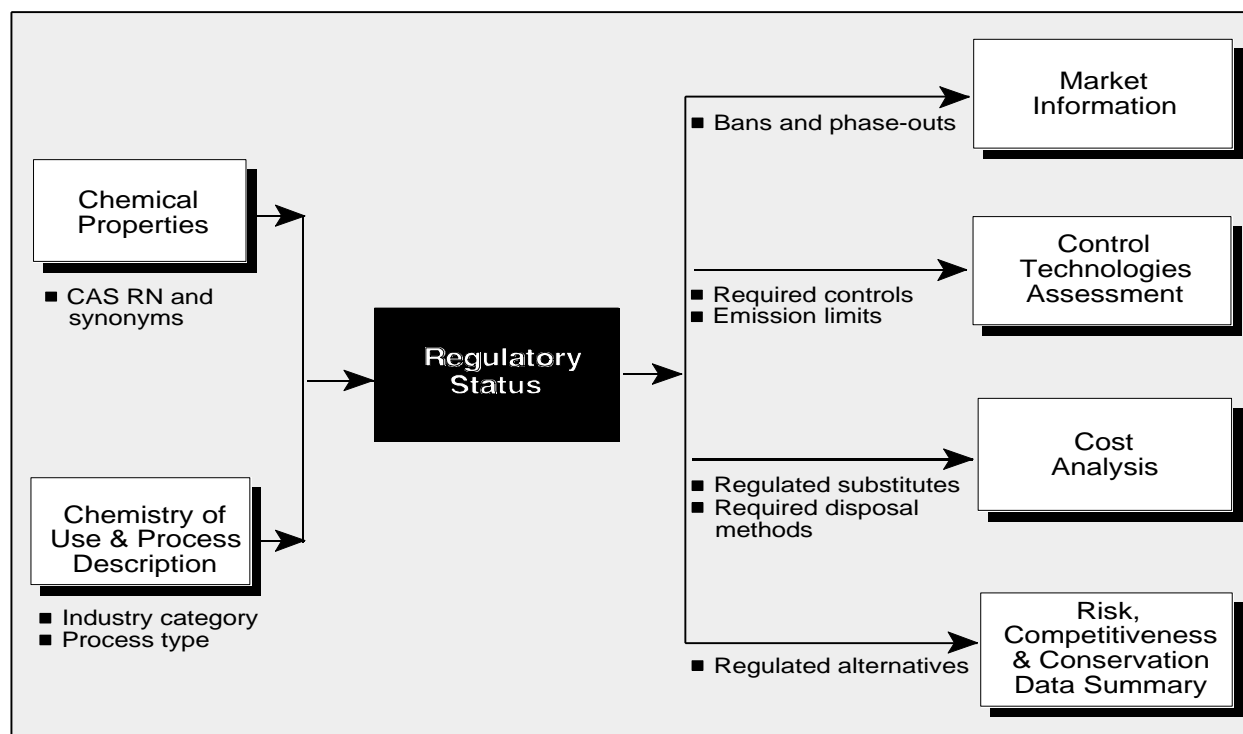
Searching Computer Data Bases

The WESTLAW® network has data bases for both the *Code of Federal Regulations* (FENV-CFR) and the *Federal Register* (FENV-FR). Within these data bases, it is possible to search by chemical name (e.g., "benzene"). However, the search may produce hundreds of citations because the computer will pull up any document within the data base where the term appears. Thus, it will be necessary to review the text of the retrieved documents to determine whether each regulation specifically regulates the substance in question or merely mentions it in passing.

The LEXIS® network can also search for federal regulations. LEXIS® is organized by libraries and files. For a general search, enter the CODES library and then choose either the CFR file for citations to the *Code of Federal Regulations* or the FEDREG file for citations to the *Federal Register*. Again, relevant citations may also appear. Both of these on-line data bases charge for the use of their service, including on-line time charges and charges for documents downloaded.

FLOW OF INFORMATION: The Regulatory Status module receives information from the Chemical Properties and Chemistry of Use & Process Description modules and transfers information to the Market Information, Control Technologies Assessment, Cost Analysis, and Risk, Competitiveness & Conservation Data Summary modules. Example information flows are shown in Figure 7-1.

**FIGURE 7-1: REGULATORY STATUS MODULE:
EXAMPLE INFORMATION FLOWS**



ANALYTICAL MODELS: None cited.

PUBLISHED GUIDANCE: Table 7-1 lists published guidance and sources of regulatory data.

TABLE 7-1: PUBLISHED GUIDANCE AND DATA SOURCES	
Reference	Type of Guidance
<i>Chemical Regulations Reporter</i> . Updated Periodically.	Looseleaf service for regulations regarding toxic chemicals.
<i>Code of Federal Regulations Index</i> . Updated Periodically.	Index to CFR providing guide to updates in Federal Register.
<i>Environment Reporter</i> . Updated Periodically.	Looseleaf service: text of federal and state laws and regulations.
<i>Environmental Law Reporter</i> . Updated Periodically.	Looseleaf service: news, statute texts.
<i>Food and Drug Law Reporter</i> . Updated Periodically.	Looseleaf service.
<i>Index to the Code of Federal Regulations</i> . Updated Periodically.	Index to CFR.
LEXIS® Network.	On-line data base of federal and state regulations and court opinions.
<i>Occupational Safety & Health Reporter</i> . Updated Periodically.	Looseleaf service.
Orloff, Neil, et. al. Updated Periodically. <i>Community Right-To-Know Handbook</i> .	Compliance guide to EPCRA.
Stever, Donald W. Updated Periodically. <i>Law of Chemical Regulation & Hazardous Waste</i> .	Comprehensive legal treatise.
<i>Suspect Chemicals Sourcebook</i> . Updated Periodically.	Regulatory analysis by chemical.
<i>United States Code</i> . Updated Periodically.	Official text of federal statutes.
<i>United States Code Annotated</i> . Updated Periodically.	Text of federal statutes with annotations.
<i>United States Code Service</i> . Updated Periodically.	Text of federal statutes with annotations.
U.S. Environmental Protection Agency. 1994b. <i>Federal Environmental Regulations Potentially Affecting the Commercial Printing Industry</i> .	Regulatory profile of the commercial printing industry.

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TABLE 7-1: PUBLISHED GUIDANCE AND DATA SOURCES	
Reference	Type of Guidance
WESTLAW® Network.	On-line data base of federal and state regulations and court opinions.

Note: References are listed in shortened format, with complete references given in the reference list following Chapter 10.

DATA SOURCES: None cited.